

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

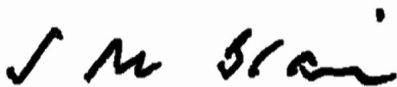
No. CE 667673
Issued To: **Medica Holdings, LLC**
5200 Meadows Road, Suite 150
Lake Oswego
Oregon
97035
USA

In respect of:

Design and manufacture of non-sterile, single patient, reusable positive expiratory pressure device intended to improve clearance of bronchial mucus secretions.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2017-12-03**

Date: **2018-02-21**

Expiry Date: **2022-12-02**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:

Service(s) supplied

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

EU Representative

Engineered Medical Systems, Inc.
2055 Executive Drive
Indianapolis
Indiana
46241
USA

Finished Device Supplier

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
03 December 2017	8675084	First issue.
Current	8903631	Change of EU representative to Emergo Europe.